NOTICE OF INTENT

Department of Environmental Quality
Office of Environmental Assessment
Environmental Planning Division

Medical Use of Radioactive Material
(LAC 33:XV.102, 104, 492, 703, 704, 709, 710, 712, 715, 716, 717, 719, 726, 728, 729, 731, 735, 736, 737, 739, 741, 742, 743, 744, 745, 747, 748, 750, 751, 755, 756, 757, 758, 759, 762, 763, and 777) (RP034*)

Under the authority of the Environmental Quality Act, R.S. 30:2001 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the secretary gives notice that rulemaking procedures have been initiated to amend the Radiation Protection regulations, LAC 33:XV.102, 104, 492, 703, 704, 709, 710, 712, 715, 716, 717, 719, 726, 728, 729, 731, 735, 736, 737, 739, 741, 742, 743, 744, 745, 747, 748, 750, 751, 755, 756, 757, 758, 759, 762, 763, and 777 (Log #RP034*).

This proposed rule is identical to federal regulations found in 68 FR 19466-19470 (April 21, 2003); 67 FR 62872 (October 9, 2002); and 67 FR 20349-20397 (April 24, 2002), which are applicable in Louisiana. For more information regarding the federal requirement, contact the Regulation Development Section at (225) 219-3550 or Box 4314, Baton Rouge, LA 70821-4314. No fiscal or economic impact will result from the proposed rule; therefore, the rule will be promulgated in accordance with R.S. 49:953(F)(3) and (4).

This proposed rule amends regulations regarding the medical use of radioactive material. The rule focuses on those medical procedures that pose the highest risk to workers, patients, and the public, and structures the regulations to be more risk-informed and performance-based. This rulemaking is necessary to maintain delegation and authorization granted to Louisiana by the Nuclear Regulatory Commission and the Environmental Protection Agency and to keep Louisiana's radiation protection program current with its federal counterpart. The basis and rationale for this rule are to mirror the federal regulations and to protect and inform the workers, patients, and public regarding medical procedures that pose the highest risk.

This proposed rule meets an exception listed in R.S. 30:2019(D)(2) and R.S. 49:953(G)(3); therefore, no report regarding environmental/health benefits and social/economic costs is required. This proposed rule has no known impact on family formation, stability, and autonomy as described in R.S. 49:972.

A public hearing will be held on May 25, 2004, at 1:30 p.m. in the Galvez Building, Oliver Pollock Conference Room C111, 602 N. Fifth Street, Baton Rouge, LA 70802. Interested persons are invited to attend and submit oral comments on the proposed amendments. Should individuals with a disability need an accommodation in order to participate, contact Judith A. Schuerman, Ph.D., at the address given below or at

(225) 219-3550. Free parking is available across the street in the Galvez parking garage when the parking ticket is validated by department personnel at the hearing.

All interested persons are invited to submit written comments on the proposed regulation. Persons commenting should reference this proposed regulation by RP034*. Such comments must be received no later than May 25, 2004, at 4:30 p.m., and should be sent to Judith A. Schuerman, Ph.D., Office of Environmental Assessment, Environmental Planning Division, Regulation Development Section, Box 4314, Baton Rouge, LA 70821-4314 or to FAX (225) 219-3582 or by e-mail to judith.schuerman@la.gov. The comment period for this rule ends on the same date as the public hearing. Copies of this proposed regulation can be purchased by contacting the DEQ Public Records Center at (225) 219-3168. Check or money order is required in advance for each copy of RP034*.

This proposed regulation is available for inspection at the following DEQ office locations from 8 a.m. until 4:30 p.m.: 602 N. Fifth Street, Baton Rouge, LA 70802; 1823 Highway 546, West Monroe, LA 71292; State Office Building, 1525 Fairfield Avenue, Shreveport, LA 71101; 1301 Gadwall Street, Lake Charles, LA 70615; 201 Evans Road, Building 4, Suite 420, New Orleans, LA 70123; 111 New Center Drive, Lafayette, LA 70508; 104 Lococo Drive, Raceland, LA 70394 or on the Internet at http://www.deq.louisiana.gov/planning/regs/index.htm.

James H. Brent, Ph.D.
Assistant Secretary

Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 1. General Provisions

§102. Definitions and Abbreviations

As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain chapter may be found in that chapter.

***

Address of Use—the building or buildings that are identified on the license and where radioactive material may be received, prepared, used, or stored.

***

Authorized Medical Physicist—an individual who is identified as an authorized medical physicist or teletherapy physicist on:

1. a specific medical use license issued by the department, the U.S. Nuclear Regulatory Commission, or an agreement state;
2. a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee;
3. a permit issued by the department, the U.S. Nuclear Regulatory Commission, or an agreement state broad scope medical use licensee; or
4. a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

***

Brachytherapy Source—a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

***

Client's Address—the area of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with LAC 33:XV.726.

***

Dentist—an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

***

High Dose-Rate Remote Afterloader—a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

***

Low Dose-Rate Remote Afterloader—a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

***

Manual Brachytherapy—a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

Medical Event—an event that meets the criteria in LAC 33:XV.712.A.

***

Medium Dose-Rate Remote Afterloader—a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads), per hour at the point or surface where the dose is prescribed.

***

Metric Prefixes and Abbreviations—

c	centi	$(=10^{-2})$	f	femto	$(=10^{-15})$
m	milli	$(=10^{-3})$	k	kilo	$(=10^{3})$
μ	micro	$(=10^{-6})$	M	mega	$(=10^{6})$
n	nano	$(=10^{-9})$	G	giga	$(=10^{9})$
p	pico	$(=10^{-12})$	T	tera	$(=10^{12})$

***

Misadministration—Repealed. ~~the administration of:~~

~~1. a radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:~~

~~a. involving the wrong individual or wrong radiopharmaceutical; or~~

~~b. when both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.~~

~~2. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:~~

~~a. involving the wrong individual, wrong pharmaceutical, or wrong route of administration; or~~

~~b. when the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.~~

~~3. A gamma stereotactic radiosurgery radiation dose:~~

~~a. involving the wrong individual or wrong treatment site; or~~

~~b. when the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.~~

~~4. A teletherapy radiation dose:~~

~~a. involving the wrong individual, wrong mode of treatment, or wrong treatment site;~~

~~b. when the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;~~

~~c. when the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or~~

~~d. when the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.~~

~~5. A brachytherapy radiation dose:~~

~~a. involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);~~

~~b. involving a sealed source that is leaking;~~

~~c. when, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or~~

~~d. when the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.~~

~~6. A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:~~

~~a. involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and~~

~~b. when the dose to the individual exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.~~

Mobile Medical Service—the transportation of radioactive material to, and its medical use at, the client's address.

***

Output—the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy unit, a remote afterloader, or a gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

***

Patient Intervention—actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

***

Physician—~~an individual who possesses a certificate to practice medicine issued~~ a medical doctor or doctor of osteopathy licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine, or who is authorized to practice medicine under the provisions of R.S. 37:1261 et seq.

Podiatrist—an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

Preceptor—an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

***

Prescribed Dose—

1.-2. …

3. for manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

4. for remote brachytherapy afterloaders, the total dose and dose per fraction in the written directive.

***

Pulsed Dose-Rate Remote Afterloader—a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

1. is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

2. is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

***

Sealed Source and Device Registry—the national registry that contains all the registration certificates, generated by both the U.S. Nuclear Regulatory Commission and the agreement states, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the products.

***

Stereotactic Radiosurgery—the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

Structured Educational Program—an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

***

Therapeutic Dosage—a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic Dose—a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

***

Treatment Site—the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of Use—use of radioactive material as described in LAC 33:XV.729, 731, 735, 739, 741, or 747.

***

Unit Dosage—a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

***

Year—the period of time beginning in January used to determine compliance with the provisions of these regulations. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that

the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

~~The following metric prefixes and abbreviations are used in these regulations:~~

~~c~~	~~centi~~	~~(=10^{-2})~~	~~f~~	~~femto~~	~~(=10^{-15})~~
~~m~~	~~milli~~	~~(=10^{-3})~~	~~k~~	~~kilo~~	~~(=10^{3})~~
~~μ~~	~~micro~~	~~(=10^{-6})~~	~~M~~	~~mega~~	~~(=10^{6})~~
~~n~~	~~nano~~	~~(=10^{-9})~~	~~G~~	~~giga~~	~~(=10^{9})~~
~~p~~	~~pico~~	~~(=10^{-12})~~	~~T~~	~~tera~~	~~(=10^{12})~~

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 19:1421 (November 1993), LR 20:650 (June 1994), LR 22:967 (October 1996), LR 24:2089 (November 1998), repromulgated LR 24:2242 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2563 (November 2000), LR 26:2767 (December 2000), LR 30:

§104. Records

A.-C. …

D. Each licensee and registrant shall maintain the records required by LAC 33:XV.104, 421, ~~and~~ 451, and all other applicable portions of these regulations at the authorized location of storage and/or use.

E. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

Chapter 4. Standards for Protection Against Radiation

Subchapter J. Reports

§492. Reports of Leaking or Contamination From Sealed Sources

A. The licensee or registrant shall file a report within five days with the Office of Environmental Compliance~~, or e-mail at surveillance@deq.state.la.us~~ using the procedures provided in LAC 33:I.3925 if the test for leakage or contamination required ~~pursuant to~~ in accordance with LAC 33:XV.426 indicates a sealed source is leaking or a source of contamination. The report shall include the equipment involved, its model number and serial number if assigned, the estimated activity of the source, the test results, the date of the test, and the corrective action taken.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2580 (November 2000), LR 30:

Chapter 7. Use of Radionuclides in the Healing Arts

§703. License Amendments and Provisions for Research Involving Human Subjects

A.-A.6 …

B. ~~Provisions for Research Involving Human Subjects.~~ A licensee may conduct research involving human subjects using radioactive material, provided that the research is conducted, funded, supported, or regulated by a federal agency that has implemented the Federal Policy for the Protection of Human Subjects. ~~Otherwise, a licensee shall apply for and receive approval of a specific amendment to its department license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.~~

C. If the research will not be conducted, funded, supported, or regulated by a federal agency that has implemented the Federal Policy for the Protection of Human Subjects, the licensee shall, before conducting research, apply for and receive a specific amendment to its U.S. Nuclear Regulatory Commission medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

1. obtain review and approval of the research from an *Institutional Review Board*, as defined and described in the Federal Policy; and

2. obtain *informed consent*, as defined and described in the Federal Policy, from the human research subject.

D. Nothing in this Section relieves licensees from complying with the other requirements in this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2101 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2587 (November 2000), LR 30:

§704. Notifications

A.-B. …

1. an authorized user, an authorized nuclear pharmacist, a radiation safety officer, or an ~~teletherapy~~ authorized medical physicist permanently discontinues performance of duties under the license or has a name change; or

2. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2101 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2587 (November 2000), LR 30:

§709. Supervision

A.-A.1. …

2. require the supervised individual to follow the instructions of the supervising authorized user, written radiation protection procedures established by the licensee, written directive procedures, regulations of this Chapter, and license conditions with respect to the medical use of radioactive material;

~~2~~3. review the supervised individual's use of radioactive material, provide reinstruction as needed, and review records kept to reflect this use;

~~3~~4. require the authorized user to be immediately available to communicate with the supervised individual;

~~4~~5. require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice (~~t~~The supervising authorized user need not be present for each use of radioactive material.); and

~~5~~6. require that only those individuals specifically trained, and designated by the authorized user, shall be permitted to administer radionuclides or radiation to patients.

B.-D. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and

repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2102 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§710. Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child

A. A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

B. A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

1. is greater than 50 mSv (5 rem) total effective dose equivalent; or

2. has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

C. The licensee shall notify the Office of Environmental Compliance in the manner provided in LAC 33:I.3923 no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with Subsection A or B of this Section.

D. The licensee shall submit a written report to the Office of Environmental Compliance in the manner provided in LAC 33:I.3925 within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with Subsection A or B of this Section.

1. The written report shall include:

a. the licensee's name;

b. the name of the prescribing physician;

c. a brief description of the event;

d. why the event occurred;

e. the effect, if any, on the embryo/fetus or the nursing child;

f. what actions, if any, have been taken or are planned to be taken to prevent recurrence; and

g. certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) in accordance with Subsection E of this Section and, if not, why not.

2. The report shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

E. The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as "the mother," no later than 24 hours after discovery of an event that would require reporting in accordance with Subsection A or B of this Section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay

any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this Subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of to the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

F. A licensee shall:

1. annotate a copy of the report provided to the Office of Environmental Compliance, SPOC with:

a. the name of the pregnant individual or the nursing child who is the subject of the event; and

b. the social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

2. provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, Environmental Planning Division, LR 30:

§712. Notifications, Reports, and Records of ~~Misadministrations~~ Medical Events

A. A licensee shall report any medical event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

1. a dose that differs from the prescribed dose, or the dose that would have resulted from the prescribed dosage, by more than 0.05 Sv (5 rem) effective dose equivalent, (0.5 Sv (50 rem) to an organ or tissue), or 0.5 Sv (50 rem) shallow dose equivalent to the skin, where:

a. the total dose delivered differs from the prescribed dose by 20 percent or more;

b. the total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

c. the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;

2. a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

a. an administration of a wrong radioactive drug;

b. an administration of a radioactive drug by the wrong route of administration;

c. an administration of a dose or dosage to the wrong individual or human research subject;

d. an administration of a dose or dosage delivered by the wrong mode of treatment; or

e. a leaking sealed source; or

3. a dose to the skin or an organ or tissue other than the treatment site that exceeds 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

B. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

~~A~~C. ~~For a misadministration:~~The following notifications are required for a medical event.

1. ~~t~~The licensee shall notify ~~by telephone~~ the Office of Environmental Compliance ~~at (225) 765-0160~~ in the manner provided in LAC 33:I.3923 no later than the next calendar day after discovery of the ~~misadministration;~~ medical event.

2. ~~t~~The licensee shall submit a written report to the Office of Environmental Compliance using the procedures in LAC 33:I.3925 within 15 days after discovery of the ~~misadministration~~ medical event. The written report shall include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the administration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual, or the individual's responsible relative or guardian ~~(this person will be subsequently referred to as "the individual" in this Section)~~, and if not, why not~~,~~; and if the individual was notified, what information was provided to the individual. The report shall not include the individual's name or other information that could lead to identification of the individual. To meet the requirements of this Section, the notification of the ~~individual receiving the misadministration~~ medical event may be made to the individual or instead to that individual's responsible relative or guardian, when appropriate~~;~~.

3. ~~t~~The licensee shall notify the referring physician and also notify the individual who is the subject of the medical event ~~receiving the misadministration~~ no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual ~~receiving the misadministration~~ cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the ~~misadministration~~ medical event, because of any delay in notification~~;~~. To meet the requirements of this Paragraph, the notification to the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written

description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

4. ~~i~~If the individual was notified, the licensee shall also furnish, within 15 days after discovery of the ~~misadministration~~ medical event, a written report to the individual by sending either:

a. a copy of the report that was submitted to the department; or

b. a brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the department can be obtained from the licensee.

D~~B~~. Each licensee shall retain a record of each ~~misadministration~~ medical event for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual ~~who received the misadministration~~ affected by the medical event, and the individual's referring physician), the individual's social security number or identification number if one has been assigned, a brief description of the ~~misadministration~~ medical event, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

E~~C~~. Aside from the notification requirement, nothing in this Section affects any rights or duties of licensees and physicians in relation to each other, the individual, or the individual's responsible relatives or guardians.

F. A licensee shall:

1. annotate a copy of the report provided to the department with:

a. the name of the individual who is the subject of the event; and

b. the social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

2. provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2102 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2588 (November 2000), LR 30:

§715. Possession, Use, Calibration, and Checking of Dose Calibrators and of Instruments to Measure Dosages of Alpha-Emitting or Beta-Emitting Radionuclides

A. ~~A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the activity of dosages of photon-emitting radionuclides prior to administration to each patient or human research subject.~~ For direct measurements performed in accordance with LAC 33:XV.717, a licensee shall

possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

B.-C. …

D. A licensee shall also perform checks and tests required by ~~LAC 33:XV.715.B~~ Subsection B of this Section following adjustment or repair of the dose calibrator.

E. A licensee shall retain a record of each check and test required by ~~LAC 33:XV.715~~ this Section for two years. The records for the checks and tests required by ~~LAC 33:XV.715.B.~~ Subsection B of this Section shall include:

1. for ~~LAC 33:XV.715.B.1~~ Paragraph B.1 of this Section, the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

2. for ~~LAC 33:XV.715.B.2~~ Paragraph B.2 of this Section, the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the radiation safety officer;

3. for ~~LAC 33:XV.715.B.3~~ Paragraph B.3 of this Section, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the radiation safety officer; and

4. for ~~LAC 33:XV.715.B.4~~ Paragraph B.4 of this Section, the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the radiation safety officer.

F.-F.2.b. …

G. A licensee shall calibrate the instrumentation required in Subsection A of this Section in accordance with nationally-recognized standards or the manufacturer's instructions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2103 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§716. Calibration and Checking of Survey Instruments

A. …

B. To satisfy the requirements of ~~LAC 33:XV.716.A~~ Subsection A of this Section, the licensee shall:

1.-3. …

C. To satisfy the requirements of ~~LAC 33:XV.716.B~~ Subsection B of this Section, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument. A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than the allowed 20 percent.

D. …

E. The licensee shall retain a record of each calibration required in ~~LAC 33:XV.716.A~~ Subsection A of this Section for two years. The record shall include:

1.-2. …

F. To meet the requirements of ~~LAC 33:XV.716.A, B, and C~~ Subsections A, B, and C of this Section, the licensee may obtain the services of individuals licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations that contain information required by ~~LAC 33:XV.716.E~~ Subsection E of this Section shall be maintained by the licensee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2589 (November 2000), LR 30:

§717. Assay of Radiopharmaceutical Dosages

~~A licensee shall do the following:~~

~~A. assay, within 30 minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than 10 microcuries (370 kBq) of a photon-emitting radionuclide;~~

~~B. assay, before medical use, the activity of the radiopharmaceutical dosage with a desired activity of 10 microcuries (370 kBq) or less of a photon-emitting radionuclide to verify that the dosage does not exceed 10 microcuries (370 kBq);~~

~~C. assay before medical use, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha-emitting or a beta- emitting radionuclide, except for unit dosages obtained from a manufacturer or preparer licensed in accordance with LAC 33:XV.Chapter 3, equivalent agreement state, or Nuclear Regulatory Commission requirements;~~

~~D. retain a record of the assays required by Subsections A, B, and C of this Section for two years. To satisfy this requirement, the record shall contain the following:~~

~~1. generic name, trade name, or abbreviation of the radiopharmaceutical; its lot number; and expiration dates and the radionuclide;~~

~~2. patient's or human research subject's name and identification number if one has been assigned;~~

~~3. prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 10 microcuries (370 Kbq);~~

~~4. date and time of the assay and administration; and~~

~~5. initials of the individual who performed the assay.~~

A. A licensee shall determine and record the activity of each dosage before medical use.

B. For a unit dosage, this determination shall be made by:

1. direct measurement of radioactivity; or

2. a decay correction, based on the activity or activity concentration determined by:

a. a manufacturer or preparer licensed under LAC 33:XV.328.J or equivalent agreement state requirements; or

b. a U.S. Nuclear Regulatory Commission or agreement state licensee, for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

C. For other than unit dosages, this determination shall be made by:

1. direct measurement of radioactivity;

2. a combination of measurement of radioactivity and mathematical calculations; or

3. a combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under LAC 33:XV.328.J or equivalent agreement state requirements.

D. Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

E. A licensee shall retain a record of the dosage determination required by this Section for three years. The record shall contain:

1. the radiopharmaceutical;

2. the patient's or human research subject's name or identification number, if one has been assigned;

3. the prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);

4. the date and time of the dosage determination; and

5. the name of the individual who determined the dosage.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2103 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§719. Requirements for Possession of Sealed Sources and Brachytherapy Sources

A.-B.2. …

C. To satisfy the leak test requirements of ~~LAC 33:XV.719.B~~ Subsection B of this Section, the licensee shall assure that:

C.1.-H. …

I. A licensee shall retain a record of each survey required in ~~LAC 33:XV.719.H~~ Subsection H of this Section for two years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in milliroentgens per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the radiation safety officer.

J. Before the first medical use of a brachytherapy source on or after October 24, 2002, a licensee shall have:

1. determined the source output or activity using a dosimetry system that meets the requirements of LAC 33:XV.755.A;

2. determined source positioning accuracy within applicators; and

3. used published protocols currently accepted by nationally-recognized bodies to meet the requirements of Paragraphs J.1 and J.2 of this Section.

K. A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with Subsection J of this Section.

L. A licensee shall mathematically correct the outputs or activities determined in Subsection A of this Section for physical decay at intervals consistent with 1 percent physical decay.

M. A licensee shall retain a record of each calibration in accordance with LAC 33:XV.744.B.

N. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined in accordance with Subsections J-M of this Section.

O. A licensee shall retain a record of the activity of each strontium-90 source in accordance with LAC 33:XV.744.C.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2589 (November 2000), LR 30:

§726. Mobile Medical ~~Nuclear Medicine~~ Service Technical Requirements

A. A licensee providing mobile medical ~~nuclear medicine~~ services shall do the following.

~~1. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits.~~

~~2. Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste.~~

~~3. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use.~~

~~4. Check survey instruments and dose calibrators as required in LAC 33:XV.715.B.1, D, E and 716.D, and check all other transported equipment for proper function before medical use at each location of use.~~

~~5. Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material, and before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed.~~

~~6. Retain a record of each survey required by LAC 33:XV.726.A.5 for two years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in milliroentgens per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.~~

1. Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client.

2. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this Paragraph shall include a constancy check.

3. Check survey instruments for proper operation with a dedicated check source before use at each client's address.

4. Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in LAC 33:XV.Chapter 4.

B. A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

C. A licensee providing mobile medical services shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by Paragraph A.1 of this Section. Each letter shall be retained for three years after the last provision of service.

D. A licensee providing mobile medical services shall retain the record of each survey required by Paragraph A.4 of this Section for three years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation

Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§728. Decay-in-Storage

A.-A.2. …

3. removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

4. …

B. For radioactive material disposed in accordance with ~~LAC 33:XV.728.A~~ Subsection A of this Section, the licensee shall retain a record of each disposal for two years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 27:1238 (August 2001), LR 30:

§729. Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies

A.-A.7. …

B. A licensee using a radiopharmaceutical specified in ~~LAC 33:XV.729.A~~ Subsection A of this Section for a clinical procedure other than one specified in the product label or package insert instructions shall comply with the product label or package insert instructions regarding physical form, route of administration, and dosage range.

C. The radiopharmaceuticals specified in Subsection A of this Section shall be ~~either~~:

1. obtained from a manufacturer or preparer licensed in accordance with LAC 33:XV.328.J or equivalent Nuclear Regulatory Commission~~,~~ or agreement state requirements; ~~or~~

2. prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in LAC 33:XV.763.C, or an individual under the supervision of either as specified in LAC 33:XV.709~~.~~;

3. obtained from and prepared by a Nuclear Regulatory Commission or agreement state licensee, for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

4. prepared by the licensee, for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2104 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§731. Use of Radiopharmaceuticals, Generators, and Reagent Kits For Imaging and Localization Studies

A.-C. …

D. Technetium-99m pentetate as an aerosol for lung function studies is not subject to the restrictions in ~~LAC 33:XV.731.B~~ Subsection B of this Section.

E.-F.2. …

G. Except for quantities that require a written directive in accordance with LAC 33:XV.777.B, a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

1. obtained from a manufacturer or preparer licensed under LAC 33:XV.328.J or equivalent agreement state requirements;

2. prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in LAC 33:XV.763.D, or an individual under the supervision of either as specified in LAC 33:XV.709;

3. obtained from and prepared by a Nuclear Regulatory Commission or agreement state licensee, for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

4. prepared by the licensee, for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2104 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2589 (November 2000), LR 27:1238 (August 2001), LR 30:

§735. Use of Radiopharmaceuticals for Therapy

A.-B.2. …

C. A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

1. obtained from a manufacturer or preparer licensed under LAC 33:XV.328.J or equivalent agreement state requirements;

2. prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in LAC 33:XV.763.E, or an individual under the supervision of either as specified in LAC 33:XV.709;

3. obtained from and prepared by a Nuclear Regulatory Commission or agreement state licensee, for use in research in accordance with an IND protocol accepted by FDA; or

4. prepared by the licensee, for use in research in accordance with an IND protocol accepted by FDA.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2104 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§736. Safety Instruction

A.-B.1. …

2. visitor control, including: ~~.~~

a. routine visitation to hospitalized individuals in accordance with LAC 33:XV.421.A.1; and

b. visitation authorized in accordance with LAC 33:XV.421.C;

3.-6. …

C. A licensee shall keep a record of individuals receiving instruction required by ~~LAC 33:XV.736.A~~ Subsection A of this Section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the department for two years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2105 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2589 (November 2000), LR 30:

§737. Safety Precautions

A. …

1. quarter the patient or human research subject either in:

a. ~~provide~~ a private room with a private sanitary facility; or

b. a room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under LAC 33:XV.725;

A.2.-B. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2105 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2589 (November 2000), LR 30:

§739. Use of Sealed Sources for Diagnosis

A. ~~A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:~~

~~1. iodine-125 as a sealed source in a device for bone mineral analysis;~~

~~2. americium-241 as a sealed source in a device for bone mineral analysis;~~

~~3. gadolinium-153 as a sealed source in a device for bone mineral analysis; and~~

~~4. iodine-125 as a sealed source in a portable device for imaging.~~

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§741. Use of Sources for Brachytherapy

A.-A.5. …

B. A licensee shall use only radioactive sources for therapeutic medical uses:

1. as approved in the Sealed Source and Device Registry; or

2. in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA, provided the requirements of LAC 33:XV.713.A.1 are met.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§742. Safety Instructions

A. …

B. To satisfy ~~LAC 33:XV.742.A~~ the requirements of Subsection A of this Section, the instruction shall describe:

1.-3. …

4. procedures for visitor control~~.~~, including:

a. routine visitation of hospitalized individuals in accordance with LAC 33:XV.421.A.1; and

b. visitation authorized in accordance with LAC 33:XV.421.C;

5.-6. …

C. A licensee shall maintain a record of individuals receiving instruction required by ~~LAC 33:XV.742.A~~ Subsection A of this Section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for two years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2105 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§743. Safety Precautions

A.-A.4. …

B. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

1. dislodged from the patient; or

2. lodged within the patient following removal of the source applicators.

~~B.~~C. A licensee shall notify the radiation safety officer or authorized user immediately if the patient or human research subject dies or has a medical emergency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and

repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2105 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§744. Brachytherapy ~~Sources Inventory~~ Records

A. Brachytherapy Sources Inventory

1. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

~~A~~2. Promptly after removing them from a patient or a human research subject, the licensee shall return brachytherapy sources to an area of storage from the area of use, and immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

~~B~~3. A licensee shall make a record of brachytherapy source utilization that includes:

~~1~~a. the names of the individuals permitted to handle the sources;

~~2~~b. the number and activity of sources removed from storage, the room number of use and the patient's or human research subject's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

~~3~~c. the number and activity of sources returned to storage, the room number of use and the patient's or human research subject's name, the time and date ~~they~~ the sources were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

~~C~~4. Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

~~D~~5. A licensee shall maintain the records required in ~~LAC 33:XV.744.B and C~~ Paragraphs A.3 and 4 of this Section for two years.

B. Records of Calibration Measurements of Brachytherapy Sources

1. A licensee shall maintain a record of the calibrations of brachytherapy sources required by LAC 33:XV.719 for three years after the last use of the source.

2. The record shall include:

a. the date of the calibration;

b. the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

c. the source output or activity;

d. the source positioning accuracy within the applicators; and

e. the signature of the authorized medical physicist.

C. Records of Decay of Strontium-90 Sources for Ophthalmic Treatments

1. A licensee shall maintain a record of the activity of a strontium-90 source required by LAC 33:XV.719 for the life of the source.

2. The record shall include:

a. the date and initial activity of the source as determined in accordance with LAC 33:XV.719; and

b. for each decay calculation, the date and the source activity as determined in accordance with LAC 33:XV.719.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2106 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§745. ~~Release of Patients or Human Research Subjects Treated with~~ Surveys for Temporary Implants

A. Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

~~A~~B. Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall perform a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.

C. Before releasing a patient or a human research subject treated with a remote afterloader unit from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the sources have been removed from the patient or human research subject and returned to the safe shielded position.

~~B~~D. A licensee shall maintain a record of patient or human research subject surveys that demonstrates compliance with Subsections A, B, and C of this Section for two years. Each record shall include the date and results of the survey, the survey instrument used ~~name of the patient or human research subject, the dose rate from the patient or human research subject expressed as milliroentgens per hour and measured within one meter from the patient or human research subject~~, and the ~~initials~~ name of the individual who made the survey.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation

Protection Division, LR 18:34 (January 1992), amended LR 24:2106 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§747. Use of ~~a~~ Sealed Sources in ~~a~~ Teletherapy Units, Remote Afterloader Units, and Gamma Stereotactic Radiosurgery Units

A. A licensee shall use ~~cobalt-60 or cesium-137 as a~~ sealed sources in ~~a~~ teletherapy units, photon emitting remote afterloader units, or gamma stereotactic radiosurgery units for therapeutic medical uses: ~~in accordance with the manufacturer's radiation safety and operating instructions~~

1. as approved in the Sealed Source and Device Registry; or

2. in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA, provided the requirements of LAC 33:XV.713.A.1 are met.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§748. Maintenance and Repair Restrictions

A. …

B. Except for low dose-rate remote afterloader units, only a person specifically licensed by the department, the U.S. Nuclear Regulatory Commission, or an agreement state shall install, replace, relocate, or remove a sealed source or a source contained in a remote afterloader unit, a teletherapy unit, or a gamma stereotactic radiosurgery unit.

C. For a low dose-rate remote afterloader unit, only a person specifically licensed by the department, the U.S. Nuclear Regulatory Commission, or an agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source contained in the unit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2590 (November 2000), LR 30:

§750. Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

A. For remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, a licensee shall:

1. secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

2. permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source;

3. prevent dual operation of more than one radiation-producing device in a treatment room, if applicable; and

4. develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures shall include:

a. instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

b. the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

c. the names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

B. A copy of the procedures required by Paragraph A.4 of this Section shall be physically located at the unit console.

~~A~~C. A licensee shall conspicuously post written instructions at the ~~teletherapy~~ unit console. These instructions shall inform the operator of:

1. ~~the procedure to be followed to ensure that only the patient or human research subject is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption~~ the location of the procedures required by Paragraph A.4 of this Section; and

~~2. the procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or if any other abnormal operation occurs; and~~

2~~3~~. the names and telephone numbers of the authorized users, the authorized medical physicist, and radiation safety officer to be immediately contacted if the ~~teletherapy~~ unit or console operates abnormally.

~~B~~D. A licensee shall provide instruction, initially and at least annually, ~~in the topics identified in LAC 33:XV.750.A~~ to all individuals who operate ~~a teletherapy~~ the unit, as appropriate to the individual's assigned duties, ~~and shall provide appropriate refresher training to individuals at intervals not to exceed one year.~~ in:

1. the procedures identified in Paragraph A.4 of this Section; and

2. the operating procedures for the unit.

E. A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

~~C~~F. A licensee shall maintain a record of individuals receiving instruction required by ~~LAC 33:XV.750.B~~ Subsection D of this Section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for two years.

G. A licensee shall retain a copy of the procedures required by Paragraph A.4 and D.2 of this Section until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2106 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§751. Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units ~~Doors, Interlocks, and Warning Systems~~

A. A licensee shall control access to the ~~teletherapy~~ treatment room by a door at each entrance.

B. A licensee shall equip each entrance to the ~~teletherapy~~ treatment room with an electrical interlock system that ~~shall~~ will:

1. prevent the operator from initiating the treatment cycle ~~turning the primary beam of radiation "on"~~ unless each treatment room entrance door is closed;

2. ~~turn the beam of radiation "off" immediately~~ cause the source to be shielded when an entrance door is opened; and

3. prevent the source from being exposed ~~primary beam of radiation from being turned "on"~~ following an interlock interruption until all treatment room entrance doors are closed and the ~~beam~~ source "on-off" control is reset at the console.

C. A licensee shall ~~equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.~~ require any individual entering the treatment room to ensure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

D. Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

E. For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments that allow for expeditious removal of a decoupled or jammed source.

F. In addition to the requirements specified in Subsections A through E of this Section, a licensee shall:

1. for medium dose-rate and pulsed dose-rate remote afterloader units, require:

a. an authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during the initiation of all patient treatments involving the unit; and

b. an authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit;

2. for high dose-rate remote afterloader units, require:

a. an authorized medical physicist and an authorized user to be physically present during the initiation of all patient treatments involving the unit; and

b. an authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit;

3. for gamma stereotactic radiosurgery units, require an authorized medical physicist and an authorized user to be physically present throughout all patient treatments involving the unit;

4. notify the radiation safety officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

G. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

1. remaining in the unshielded position; or

2. lodged within the patient following completion of the treatment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§755. Dosimetry Equipment and Therapy-Related Computer Systems

A.-A.2. …

B. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with ~~LAC 33:XV.755.A~~ Subsection A of this Section. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in ~~LAC 33:XV.755.A~~ Subsection A of this Section.

C. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include:

1. the date;

2. the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared, as required by ~~LAC 33:XV.755.A and B~~ Subsections A and B of this Section;

3. the correction factors that were determined;

4. the names of the individuals who performed the calibration, intercomparison, or comparison; and

5. evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

D. The licensee shall perform acceptance testing on the treatment planning system of a therapy-related computer system in accordance with published protocols accepted by nationally-recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

1. the source-specific input parameters required by the dose calculation algorithm;

2. the accuracy of dose, dwell time, and treatment time calculations at representative points;

3. the accuracy of isodose plots and graphic displays;

4. the accuracy of the software used to determine sealed source positions from radiographic images; and

5. the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§756. Full Calibration Measurements on Teletherapy Units, Remote Afterloader Units, and Gamma Stereotactic Radiosurgery Units

A. Full Calibration Measurements on Teletherapy Units

1. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

a~~1~~. before the first medical use of the unit;

b~~2~~. before medical use under the following conditions:

i~~a~~. whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay~~,~~;

iib. following replacement of the source or following reinstallation of the teletherapy unit in a new location~~,~~; and

iiie. following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

c3. at intervals not exceeding one year.

2B. To satisfy the requirement of ~~LAC 33:XV.756.A~~ Paragraph A.1 of this Section, full calibration measurements shall include determination of:

a1. the output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

b2. the coincidence of the radiation field and the field indicated by the light beam localizing device;

c3. the uniformity of the radiation field and its dependence on the orientation of the useful beam;

d4. timer accuracy, constancy, and linearity;

e5. "on-off" error; and

f6. the accuracy of all distance measuring and localization devices in medical use.

3C. A licensee shall use the dosimetry system described in LAC 33:XV.755 to measure the output for one set of exposure conditions. The remaining radiation measurements required in ~~LAC 33:XV.756.B.1~~ Subparagraph A.2.a of this Section may then be made using a dosimetry system that indicates relative dose rates.

4D. A licensee shall make full calibration measurements required by ~~LAC 33:XV.756.A~~ Paragraph A.1 of this Section in accordance with the procedures recommended by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in *Medical Physics*, vol. 10, number 6, 1983, pp. 741-771, and vol. 11, number 2, 1984, p. 213.

5E. A licensee shall correct mathematically the outputs determined in ~~LAC 33:XV.756.B.1~~ Subparagraph A.2.a of this Section for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137.

6F. Full calibration measurements required by ~~LAC 33:XV.756.A~~ Paragraph A.1 of this Section and physical decay corrections required by ~~LAC 33:XV.756.E~~ Paragraph A.5 of this Section shall be performed by a teletherapy physicist named on the licensee's license or authorized by a license issued by the U.S. Nuclear Regulatory Commission or an agreement state to perform such services.

7G. ~~A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light-beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance-measuring or localization device, and the~~

~~signature of the teletherapy physicist.~~ A licensee shall retain a record of each calibration in accordance with Subsection D of this Section.

B. Full Calibration Measurements on Remote Afterloader Units

1. A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

a. before the first medical use of the unit;

b. before medical use under the following conditions:

i. following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

ii. following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;

c. at intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

d. at intervals not exceeding one year for low dose-rate remote afterloader units.

2. To satisfy the requirement of Paragraph B.1 of this Section, full calibration measurements shall include, as applicable, determination of:

a. the output within 5 percent;

b. source positioning accuracy to within 1 millimeter;

c. source retraction with backup battery upon power failure;

d. length of the source transfer tubes;

e. timer accuracy and linearity over the typical range of use;

f. length of the applicators; and

g. function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

3. A licensee shall use the dosimetry system described in LAC 33:XV.755.A to measure the output.

4. A licensee shall make the full calibration measurements required by Subsection A of this Section in accordance with published protocols accepted by nationally-recognized bodies.

5. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in Paragraph B.2 of this Section, a licensee shall perform an autoradiograph of the sources to verify inventory and source arrangement at intervals not exceeding one quarter.

6. For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with Paragraphs B.1-5 of this Section.

7. A licensee shall mathematically correct the output determined in Subparagraph B.2.a of this Section for physical decay at intervals consistent with 1 percent physical decay.

8. Full calibration measurements required by Paragraph B.1 of this Section and physical decay corrections required by Paragraph B.7 of this Section shall be performed by the authorized medical physicist.

9. A licensee shall retain a record of each calibration in accordance with Subsection D of this Section.

C. Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units

1. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

a. before the first medical use of the unit;

b. before medical use under the following conditions:

i. whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

ii. following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

iii. following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

c. at intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

2. To satisfy the requirement of Paragraph C.1 of this Section, full calibration measurements shall include determination of:

a. the output within 3 percent;

b. relative helmet factors;

c. isocenter coincidence;

d. timer accuracy and linearity over the range of use;

e. "on-off" error;

f. trunnion centricity;

g. proper functioning of treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

h. proper functioning of helmet microswitches;

i. proper functioning of emergency timing circuits; and

j. proper functioning of stereotactic frames and localizing devices (trunnions).

3. A licensee shall use the dosimetry system described in LAC 33:XV.755.A to measure the output for one set of exposure conditions. The remaining radiation measurements required in Subparagraph C.2.a of this Section may be made using a dosimetry system that indicates relative dose rates.

4. A licensee shall make the full calibration measurements required by Paragraph C.1 of this Section in accordance with published protocols accepted by nationally-recognized bodies.

5. A licensee shall mathematically correct the outputs determined in Subparagraph C.2.a of this Section at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

6. Full calibration measurements required by Paragraph C.1 of this Section and physical decay corrections required by Paragraph C.5 of this Section shall be performed by the authorized medical physicist.

7. A licensee shall retain a record of each calibration in accordance with Subsection D of this Section.

D. Records of Teletherapy Unit, Remote Afterloader Unit, and Gamma Stereotactic Radiosurgery Unit Full Calibrations

1. A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by Subsections A, B, and C of this Section for three years. The record shall include:

a. the date of the calibration;

b. the manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit, the source, and the instruments used to calibrate the unit;

c. the results and an assessment of the full calibrations;

d. the results of the autoradiograph required for low dose-rate remote afterloader units; and

e. the signature of the authorized medical physicist who performed the full calibration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:

§757. Periodic Spot-~~e~~Checks

A. Periodic Spot-Checks for Teletherapy Units

1. A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit at intervals not to exceed one month.

2~~B~~. To satisfy the requirement of ~~LAC 33:XV.757.A~~ Paragraph A.1 of this Section, spot-checks shall include determination of:

a~~1~~. timer constancy and timer linearity over the range of use;

b~~2~~. "on-off" error;

c~~3~~. the coincidence of the radiation field and the field indicated by the light-beam localizing device;

d4. the accuracy of all distance-measuring and localization devices used for medical use;

e~~5~~. the output for one typical set of operating conditions; and

f~~6~~. the difference between the measurement made in ~~LAC 33:XV.757.B.5~~ Subparagraph A.2.e of this Section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

3~~C~~. A licensee shall use the dosimetry system described in LAC 33:XV.755 to make the spot-check required in ~~LAC 33:XV.757.B.5~~ Subparagraph A.2.e of this Section.

4D. A licensee shall perform spot-checks required by ~~LAC 33:XV.757.A~~ Paragraph A.1 of this Section in accordance with procedures established by the teletherapy physicist. The teletherapy physicist does not need to actually perform the output spot-check measurements.

5E. A licensee shall have the teletherapy physicist review the results of each output spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot-check. The licensee shall keep a copy of each written notification for two years.

6F. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility at intervals not to exceed one month.

7G. To satisfy the requirement of ~~LAC 33:XV.757.F~~ Paragraph A.6 of this Section, safety spot-checks shall ~~as~~ensure proper operation of:

a~~1~~. electrical interlocks at each teletherapy room entrance;

b~~2~~. electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation, restricting source housing angulation or elevation and carriage or stand travel, and operating the beam "on-off" mechanism;

c~~3~~. beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

d~~4~~. viewing systems;

e~~5~~. treatment room doors from inside and outside the treatment room; and

f~~6~~. electrically-assisted treatment room doors with the teletherapy unit electrical power turned "off."

8H. A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized to do so in writing by the department.

9I. A licensee shall promptly repair any system identified in ~~LAC 33:XV.757.G~~ Paragraph A.7 of this Section that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.

10J. A licensee shall maintain a record of each spot-check required by ~~LAC 33:XV.757.A and F~~ Paragraphs A.1 and 6 of this Section for two years. The record shall include the date of the spot-check; the manufacturer's name, model number, and serial number for both the teletherapy unit and source; the manufacturer's name, model number, and serial number of the instrument used to measure the output of the teletherapy unit; the timer constancy and linearity; the calculated "on-off" error; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the timer constancy and linearity for a typical treatment time; the calculated "on-off" error; the estimated accuracy of each distance-measuring or localization device; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors; and the signature of the individual who performed the periodic spot-check.

B. Periodic Spot-Checks for Remote Afterloader Units

1. A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

a. before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

b. before each patient treatment with a low dose-rate remote afterloader unit; and

c. after each source installation.

2. A licensee shall perform the measurements required by Paragraph B.1 of this Section in accordance with written procedures established by the authorized medical physicist. The authorized medical physicist need not actually perform the spot-check measurements.

3. A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

4. To satisfy the requirements of Paragraph B.1 of this Section, spot-checks shall, at a minimum, ensure proper operation of:

a. electrical interlocks at each remote afterloader unit room entrance;

b. source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

c. viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

d. emergency response equipment;

e. radiation monitors used to indicate the source position;

f. timer accuracy;

g clock (date and time) in the unit's computer; and

h. decayed source activity in the unit's computer.

5. If the results of the checks required in Paragraph B.4 of this Section indicate the malfunction of any system, a licensee shall lock the control console in the “off” position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

6. A licensee shall retain a record of each check required by Paragraph B.4 of this Section and a copy of the procedures required by Paragraph B.2 of this Section for three years. The records shall include:

a. the date of the spot-check;

b. the manufacturer's name, model number, and serial number for the remote afterloader unit and source;

c. an assessment of timer accuracy;

d. notations indicating the operability of entrance door electrical interlocks, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

e. the name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

7. A licensee shall retain a copy of the procedures required by Paragraph B.6 of this Section until the licensee no longer possesses the remote afterloader unit.

C. Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units

1. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

a. monthly;

b. before the first use of the unit on a given day; and

c. after each source installation.

2. A licensee shall:

a. perform the measurements required by Paragraph C.1 of this Section in accordance with written procedures established by the authorized medical physicist; and

b. have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

3. To satisfy the requirements of Subparagraph C.1.a of this Section, spot-checks shall, at a minimum:

a. ensure proper operation of:

i. treatment table retraction mechanisms, using backup battery power or hydraulic backups with the unit off;

ii. helmet microswitches;

iii. emergency timing circuits; and

iv. stereotactic frames and localizing devices (trunnions);

b. determine:

i. the output for one typical set of operating conditions measured with the dosimetry system described in LAC 33:XV.755.B;

ii. the difference between the measurement made in accordance with Clause C.3.b.i of this Section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

iii. the degree of agreement between source output and computer calculation;

iv. timer accuracy and linearity over the range of use;

v. “on-off" error; and

vi. trunnion centricity.

4. To satisfy the requirements of Subparagraphs C.1.b and c of this Section, spot-checks shall ensure proper operation of:

a. electrical interlocks at each gamma stereotactic radiosurgery room entrance;

b. source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

c. viewing and intercom systems;

d. timer termination;

e. radiation monitors used to indicate room exposures; and

f. emergency “off” buttons.

5. A licensee shall arrange for the repair of any system identified in Paragraph C.3 of this Section that is not operating properly as soon as possible.

6. If the results of the checks required in Paragraph C.4 of this Section indicate the malfunction of any system, a licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7. A licensee shall retain a record of each check required by Paragraphs C.3 and 4 of this Section for three years. The record shall include:

a. the date of the spot-check;

b. the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

c. an assessment of timer linearity and accuracy;

d. the calculated "on-off" error;

e. a determination of trunnion centricity;

f. the difference between the anticipated output and the measured output;

g. an assessment of source output against computer calculations;

h. notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency "off" buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

i. the name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

8. A licensee shall retain a copy of the procedures required by Paragraph C.2 of this Section until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

D. Additional Technical Requirements for Mobile Remote Afterloader Units

1. A licensee providing mobile remote afterloader service shall:

a. check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

b. account for all sources before departure from a client's address of use.

2. In addition to the periodic spot-checks required by Subsection B of this Section, a licensee authorized to use mobile remote afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks shall be made to verify the operation of:

a. electrical interlocks on treatment area access points;

b. source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

c. viewing and intercom systems;

d. applicators, source transfer tubes, and transfer tube-applicator interfaces;

e. radiation monitors used to indicate room exposures;

f. source positioning (accuracy); and

g. radiation monitors used to indicate whether the source has returned to a safe shielded position.

3. In addition to the requirements of periodic spot-checks in Paragraph D.2 of this Section, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

4. If the results of the checks required in Paragraph D.2 of this Section indicate the malfunction of any system, a licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

5. A licensee shall retain a record of each check required by Paragraph D.2 of this Section for three years. The record shall include:

a. the date of the check;

b. the manufacturer's name, model number, and serial number of the remote afterloader unit;

c. notations accounting for all sources before the licensee departs from a facility;

d. notations indicating the operability of entrance door electrical interlocks, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

e. the signature of the individual who performed the check.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2590 (November 2000), LR 30:

§758. Radiation Surveys ~~for Teletherapy Facilities~~

~~A. Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by LAC 33:XV.749, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with LAC 33:XV.716 to verify the following.~~

~~1. The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively.~~

~~2. With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation:~~

~~a. radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in LAC 33:XV.410; and~~

~~b. radiation levels in unrestricted areas do not exceed the limits specified in LAC 33:XV.421.A.~~

~~B. If the results of the surveys required in LAC 33:XV.758.A indicate any radiation levels in excess of the respective limit specified in this Section, the licensee shall lock the control in the "off" position and not use the unit:~~

~~1. except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or~~

~~2. until the licensee has received a specific exemption from the department.~~

~~C. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels; each dose rate measured around the teletherapy source while it is in the "off" position and the average of all measurements; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in milliroentgens (microsieverts) per hour; the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and the signature of the radiation safety officer.~~

A. A person licensed under this Chapter shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

B. The licensee shall make the survey required by Subsection A of this Section at installation of a new source and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.

C. A licensee shall maintain a record of radiation surveys of treatment units made in accordance with Subsections A and B of this Section for the duration of use of the unit. The record shall include:

1. the date of the measurements;

2. the manufacturer's name, model number, and serial number of the treatment unit, the source, and the instrument used to measure radiation levels;

3. each dose rate measured around the source while the unit is in the “off” position and the average of all measurements; and

4. the signature of the individual who performed the test.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2590 (November 2000), LR 30:

§759. Safety Spot-Checks for Teletherapy Facilities

A. A licensee shall promptly check all systems listed in LAC 33:XV.757.~~G~~ A.7 for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by LAC 33:XV.749.

B. If the results of the safety spot-checks required in ~~LAC 33:XV.759.A~~ Subsection A of this Section indicate the malfunction of any system specified in LAC 33:XV.757, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

C. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30

§762. Five-Year Inspection

A. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during ~~teletherapy~~ source replacement or at intervals not to exceed five years, whichever comes first, to ~~as~~ensure proper functioning of the source exposure mechanism.

B.-C. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2590 (November 2000), LR 30:

§763. Training

A.-D.2.b.iii. …

iv. using administrative controls to prevent ~~the misadministration~~ a medical event involving the use of unsealed radioactive material;

D.2.b.v.-I.2.b.ii. …

iii. using administrative controls to prevent ~~misadministrations~~ a medical event involving the use of radioactive material;

I.2.b.iv.-O. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2106 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2590 (November 2000), LR 30:

§777. Written Directives ~~Quality Management Program~~

A. A written directive shall be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of radioactive material, or any therapeutic dose of radiation from radioactive material. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours of the oral directive.

B. The written directive shall contain the patient's or human research subject's name and the following information:

1. for any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131, the dosage;

2. for an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131:

a. the radioactive drug;

b. the dosage; and

c. the route of administration;

3. for gamma stereotactic radiosurgery:

a. the total dose;

b. the treatment site; and

c. the values for the target coordinate settings per treatment for each anatomically distinct treatment site;

4. for teletherapy:

a. the total dose;

b. the dose per fraction;

c. the number of fractions; and

d. the treatment site;

5. for high dose-rate remote afterloading brachytherapy:

a. the radionuclide;

b. the treatment site;

c. the dose per fraction;

d. the number of fractions; and

e. the total dose; or

6. for all other brachytherapy, including low, medium, and pulsed dose-rate remote afterloaders:

a. before implantation:

i. the treatment site;

ii. the radionuclide; and

iii. the dose; and

b. after implantation but before completion of the procedure:

i. the radionuclide;

ii. the treatment site;

iii. the number of sources; and

iv. the total source strength and exposure time (or the total dose).

C. For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

1. the patient's or human research subject's identity is verified before each administration; and

2. each administration is in accordance with the written directive.

~~A. Each applicant or licensee under this Chapter, as applicable, shall establish and maintain a written quality management program to provide high confidence that by-product material or radiation from by-product material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:~~

~~1. that, prior to administration, a written directive is prepared for:~~

~~a. any teletherapy radiation dose;~~

~~b. any gamma stereotactic radiosurgery radiation dose;~~

~~c. any brachytherapy radiation dose;~~

~~d. any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; or~~

~~e. any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;~~

~~2. that, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;~~

~~3. that final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;~~

~~4. that each administration is in accordance with the written directive; and~~

~~5. that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.~~

~~B. The licensee shall:~~

~~1. develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:~~

~~a. a representative sample of patient or human research subject administrations;~~

~~b. all recordable events; and~~

~~c. all misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;~~

~~2. evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of LAC 33:XV.777.A; and~~

~~3. retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.~~

~~C. The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:~~

~~1. assembling the relevant facts including the cause;~~

~~2. identifying what, if any, corrective action is required to prevent recurrence; and~~

~~3. retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.~~

~~D. The licensee shall retain:~~

~~1. each written directive; and~~

~~2. a record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in LAC 33:XV.777.A.1 above, in an auditable form, for three years after the date of administration.~~

~~E. The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the Office of Environmental Services, Permits Division within 30 days after the modification has been made.~~

~~F. Each applicant for a new license, as applicable, shall submit to the Office of Environmental Services, Permits Division a quality management program as part of the application for a license and implement the program upon issuance of the license by the department.~~

~~G. Each existing licensee, as applicable, shall submit to the Office of Environmental Services, Permits Division by July 1, 1992 a written certification that the quality management program has been implemented along with a copy of the program.~~

~~H. If because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.)~~

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 21:554 (June 1995), amended LR 24:2110 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2591 (November 2000), LR 30: